

## REMARKS/ARGUMENTS

By the present amendment, applicants have canceled Claims 6 and 10, and amended Claims 1, 4, 7, 11, and 14. Support for including "at least one silicate" in Claims 1 and 4 is found in canceled Claim 6. Therefore, the claims remaining for consideration by the Examiner are Claims 1-5, 7-9, and 11-23.

The Examiner has rejected Claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Corvari et al. (U.S. Patent Application Publication No. 2003/0220403 A1) in view of Bentolila et al. (U.S. Patent Application No. 2004/0105891 A1).

Corvari describes modafinil compositions. Corvari does not teach or suggest modafinil particles having a defined particle size. On page 3, paragraph [0026], Corvari includes silicate salts, such as magnesium silicate, in a list of suitable glidants. However, Claim 1 of Corvari specifically excludes magnesium silicate in the modafinil compositions. In addition, none of the other claims of Corvari suggest a silicate salt. Moreover, none of the examples of Corvari use a silicate salt.

Bentolila describes modafinil compositions wherein at least 5% of the modafinil particles have a diameter greater than 200 microns. However, Bentolila does not teach or suggest using a silicate in the modafinil compositions. For example, Bentolila states in paragraph [0013] that the ingredients used to prepare the modafinil compositions are colloidal silicon dioxide, crospovidone, lactose, povidone, sodium stearyl fumarate, and talc. These same ingredients were used in preparing the modafinil compositions of the examples in Bentolila.

In contrast to the teachings of Corvari and Bentolila, applicants' claims, as amended, include at least one silicate and greater than 5% to about 50% of the cumulative total of the modafinil particles in the composition have a particle size greater than about 200 microns as determined by a U.S. Sieve No. 75. As stated on page 2, lines 17-21, of applicants' specification, as originally filed, applicants unexpectedly determined that applicants' compositions (see Example 1) exhibit comparable stability, dissolution and bioavailability as compared to Provigil<sup>®</sup>, which is a commercially available modafinil composition.

As noted above, Corvari does not describe a particle size parameter. In addition, Corvari teaches away in the claims and examples from using a silicate in the modafinil compositions. Bentolila describes a particle size parameter but does not teach or suggest using a silicate in the modafinil compositions. Thus, one skilled in the art combining the teachings of Corvari and Bentolila may incorporate the particle size parameters of Bentolila into the modafinil compositions of Corvari, however, according to the teachings of both references, a silicate would not be used.

In view of the above amendments and arguments, it should be unambiguously clear that none of references cited by the Examiner evaluated alone or in combination suggest applicants' modafinil composition, as claimed.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7945

  
John D. Thallemer  
Attorney for Applicants  
Reg. No. 34,940

Date: January 5, 2005